

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, <u>et al.</u> ,)	
)	Case No. 00-CV-737
)	
Plaintiffs,)	
)	
v.)	
)	
MERCK-MEDCO MANAGED)	
CARE, L.L.C., and)	
MEDCO HEALTH SOLUTIONS, INC.)	JURY TRIAL DEMANDED
MERCK MEDCO RX SERVICES OF FLORIDA,)	
NO. 2, L.C.; MEDCO HEALTH RX SERVICES)	HON. CLARENCE C. NEWCOMER
OF FLORIDA, L.C.; MERCK-MEDCO RX)	
SERVICES OF NEVADA, INC.;)	
MERCK-MEDCO RX SERVICES OF TEXAS,)	
L.L.C., ROBERT J. BLYSKAL; and)	
DIANE M. COLLINS,)	
)	
Defendants.)	

AMENDED COMPLAINT

I
Introduction

1. Plaintiff, the United States of America, brings this civil action for damages, penalties, and injunctive relief. The claims of the United States arise under the False Claims Act, 31 U.S.C. § 3729 et seq., the Fraud Injunction statute, 18 U.S.C. § 1345, the Anti-Kickback Act, 41 U.S.C. 51, et seq., and the principles of common law and equity. The government's claims arise out of a systematic pattern of conduct by defendant, Medco Health Solutions, Inc., and its affiliated companies over at least the past eight years. Medco Health Solutions, Inc. has defrauded patients, clients, and the United States by cancelling

and destroying prescriptions, by failing to perform the professional pharmacists' services needed by patients and required by law, by switching patients' prescriptions to different drugs without their knowledge and consent, by shipping medications and billing patients for drugs they never ordered, by creating false records of contact with physicians, by soliciting and receiving inducements from pharmaceutical manufacturers to favor their products by paying kickbacks to obtain contracts by making improper payments to obtain Medicare contracts, and by making false and misleading statements to the United States about its conduct.

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1345 and 31 U.S.C. § 3732(a). Venue is proper in this district because Medco Health Solutions, Inc. transacts business in this district.

A. Defendants

3. Defendant, Medco Health Solutions, Inc. ("Medco Health"), is a Delaware Limited Liability Corporation with business facilities located in 12 states, including Pennsylvania. It is the corporate successor and alter ego of defendant Merck Medco Managed Care, L.L.C. It is licensed to do business in Pennsylvania and may be found in this district. Programs managed by Medco Health provide prescription drug services to persons within this district and elsewhere, including Medicare

beneficiaries receiving medical benefits through the Medicare + Choice program, and employees of private employers and state and local governments whose benefits are paid in whole or in part by the United States. Medco Health also provides mail order prescription drug benefits for federal health programs for employees, dependents and retirees, including but not limited to the Federal Employees Health Benefits Program ("FEHBP"), Government Employees Hospital Association, Inc. ("GEHA"), the National Association of Letter Carriers ("NALC"), the American Postal Workers Union ("APWU"), the Special Agents Mutual Benefit Association ("SAMBA"), Retired Military Officers, the National Mail-Order Pharmacy (known as the "NMOP"), a mail order pharmacy benefit offered to active duty military beneficiaries, Defense Department CHAMPUS and TRICARE beneficiaries, and Tennessee Valley Authority employees and their families; as well as numerous other federal and state plans. It has operated two licensed mail order or mail-in pharmacies within the Commonwealth of Pennsylvania.

4. Medco Health operates prescription drug mail order pharmacies under the names of wholly owned subsidiaries including, but not limited to, Merck-Medco Managed Care of California, Inc.; Defendant, Merck-Medco Rx Services of Florida No. 2, L.C. ("Tampa II"); Defendant, Merck-Medco Rx Services of Florida, L.C. ("Tampa I"); Merck-Medco Rx Services of

Massachusetts, L.L.C.; Defendant, Merck-Medco Rx Services of Nevada, Inc.; Merck-Medco Rx Services of New Jersey, L.L.C.; Merck-Medco Rx Services of New York, L.L.C.; Merck-Medco Rx Services of Ohio, Ltd.; Merck-Medco Rx Services of Ohio No. 2, Ltd.; Merck-Medco Rx Services of Oklahoma, L.L.C.; Merck-Medco Rx Services of Pennsylvania, L.L.C.; Merck-Medco Rx Services of Pennsylvania No. 2, L.L.C.; Defendant, Merck-Medco Rx Services of Texas, L.L.C.; Merck-Medco Rx Services of Virginia, L.L.C.; and Merck-Medco Rx Services of Washington, Inc., (collectively "mail order pharmacies"). Each of these entities is licensed as a pharmacy under the laws of the state in which it is located, and is licensed by each state to which that mail order pharmacy ships prescriptions. Each of these entities is under the control and domination of Medco Health. The mail order pharmacies are the alter egos of Medco Health.

5. Defendant Diane M. Collins ("Collins") is a resident of the State of Florida. Until January 2001, she was employed by defendant Medco Health as the Vice President/General Manager of the Tampa II mail order pharmacy.

6. Defendant Robert J. Blyskal ("Blyskal") is a resident of the State of New Jersey. Through June 2003, he was employed as the Executive Vice President of Medco Health. He was, at relevant times, President of each of the mail order pharmacies.

B. The Pharmacy Benefit Management Business

7. Over 150 million Americans have insurance coverage that includes a pharmacy benefit. This pharmacy benefit is usually managed by a pharmacy benefit manager ("PBM"), a business which specializes in administering the patient's pharmacy benefit in return for payment by the client (usually either an employer, a health plan, a government agency, or a union). Medco Health is a PBM.

8. A PBM generally performs the following tasks:
- a. Organizing a network of retail pharmacies ("retail network") that agree to fill prescriptions for a negotiated price.
 - b. Operating a computer system which will process and pay claims, or instruct the pharmacist about denial of the claim, within minutes of submission.
 - c. Providing patients, physicians, and clients with information about the operation of their pharmacy benefit and cards or other methods to access the benefits.
 - d. Operating a mail order pharmacy which sells prescription drugs directly to patients.
 - e. Providing expert advice concerning the design of prescription drug plans, to provide a quality plan at a reasonable cost to the client and the

beneficiaries. Design issues include levels of co-payment, limits on total amount of drug spending covered, use and pricing of generic drugs, pre-authorization requirements, and formulary decision making such as and when plans should require use of older, cheaper drugs before paying for newer, more expensive drugs.

- f. Providing expert advice concerning the development and management of prescription drug formularies. Formularies are lists of preferred drugs for which a plan will pay on behalf of the beneficiary, either in whole or in part. According to the Medco Health website, "A formulary can be defined as a dynamic list of drugs and accompanying information designed to serve the health interests of patients and the economic objectives of payors." "Open formularies" permit payment for any prescription drug. "Closed formularies" limit payment to specific drugs - for example, only generics, or only one drug within a so-called "therapeutic class." "A drug's clinical merits, its efficacy, and safety profile, should be the primary basis for formulary inclusion. . . . Formulary preferences should be based on a drug's

clinical merits, and then, and only if warranted, on economics." When a drug is eligible to be on a formulary, the decision to include it "becomes a decision that Medco Health makes based upon the economic opportunities or disadvantages it may create for the plans or based upon other issues that can be drug-specific or plan-specific."

- g. Providing the services of an internal Department of Medical Affairs and an "independent pharmacy and therapeutics committee" ("P&T committee") to develop and implement clinical pharmaceutical programs.
- h. Providing expert advice and assistance in obtaining discounts or rebates from drug manufacturers.

C. The Mail Order Pharmacy Business

9. At all material times, Medco Health's mail order pharmacy clients included local, state, and federal employee and retiree groups the costs for which were paid in whole or in part by the United States, as well as private clients.

10. Mail order pharmacy benefits were provided through contracts between Medco Health and the government, or through sub-contracts entered into by entities on behalf of state and federal governments. For example, the Blue Cross and Blue Shield

Association, under the supervision of the United States Office of Personnel Management ("OPM"), has maintained a contract on behalf of four million participants in the FEHBP since 1987 with Medco Health to provide mail order pharmacy services (the "FEHBP contract").

11. Certain contracts with Medco Health for mail order pharmacy services include a number of quality assurance standards. For example, the FEHBP contract includes a guaranteed accuracy rate in filling prescriptions of less than one error in 20,000 prescriptions. In addition, the FEHBP contract includes a performance guarantee that Medco Health will dispense 99 percent of the prescriptions it receives each day within five business days of receipt.

12. Medco Health represents to clients who select it as pharmacy benefits manager that licensed pharmacists check each mail order prescription before it is sent out, as required by law, with as many as three or four quality checks.

13. The mail order pharmacy contracts between Medco Health and government programs such as FEHBP and GEHA require the performance of professional pharmacy services, such as drug utilization review ("DUR"), customer service, and counseling.

14. The provision of professional pharmacist services by a licensed pharmacy in accordance with applicable state pharmacy law is an express condition for payment for each prescription

which is sent to a Medco Health mail order pharmacy.

D. The Professional Obligations of Pharmacy Practice and Medco Health's Undertakings as a Pharmacy

15. Medco Health, itself and through the mail order pharmacies, is engaged in the practice of pharmacy and is licensed to do so under the laws of various states in which its pharmacies are located. As a licensed pharmacy, Medco Health owes certain duties to the patients whose prescriptions it receives, fills, or arranges to fill. Medco Health employs licensed professional pharmacists and licensed, certified, or designated pharmacy technicians who perform or assist in performing professional pharmacy services for patients.

16. Under Florida law and similar laws in other states, no pharmacist may dispense one or more doses of a drug to a patient unless the pharmacist, prior to the actual physical transfer of the drug:

- 1) interprets the prescription order;
- 2) assesses the prescription order for potential adverse reaction, interaction, and dosage regimen he deems appropriate in the exercise of his professional judgment;
- 3) contacts the prescriber to resolve any ambiguities in interpretation, or issues involving potential adverse reaction, interaction, or dosage;
- 4) certifies that the medicinal drug called for by the

prescription order is ready for transfer.

Under Florida law and similar laws of other states, the pharmacist must provide drug counseling to the patient, either orally or in writing, if in the exercise of his professional judgment counseling to the patient is necessary.

17. The practice of pharmacy, and the appropriate selection and modification of drug treatment regimens by physicians with the advice and assistance of professional pharmacists, has become substantially more complicated in the past twenty years. This complexity results from a vast increase in the number of categories of treatments available, a vast increase in the scientific literature relating to drug treatment options and effectiveness, and a significant increase in the number of therapeutic agents available in a given category. These increases in complexity have resulted in an increased risk of prescribing errors and adverse effects.

18. Medco Health is aware that in order to practice appropriate medicine with respect to pharmaceutical treatment, physicians adopt a variety of strategies. Specialist physicians can become "intimately familiar with all of the drugs in his or her speciality - for example, a cardiologist can explain the subtle differences between each of the dozen calcium-channel blockers." An internist, pediatrician, or primary care physician, on the other hand, "doesn't have the luxury of

narrowing his knowledge to a few diseases, so he adapts by focusing on a single medication for each disease. That strategy often fails, because to comply with multiple managed care and hospital formularies, physicians must write prescriptions for less familiar 'preferred' medicines." Medicare Pharmacy Coverage: Ensuring Safety Before Funding" by Lee N. Newcomer, M.D. in *Health Affairs*, March/April 2000.

19. Medco Health, as a licensed pharmacy, and each of its licensed mail order pharmacies, licensed pharmacists, and pharmacy technicians and customer service personnel, has a duty to provide accurate, complete, and reliable information to patients and physicians when it or its employees undertake to perform professional services relating to such patients or physicians. The dispensing of prescription medications by a licensed pharmacist gives the patient a package of product and service: the product is the prescription drug and the service is a combination of the pharmacist's monitoring of dosage quality, amounts, potential interactions with other prescriptions and over-the-counter and herbal medications, and the dispensing of advice to patients. The licensed pharmacist dispensing a prescription drug undertakes to provide the patient that combination of product and service, and the payment received by Medco Health is for both the product and the professional service.

20. Medco Health, as the owner and alter ego of licensed pharmacies, and each of its licensed mail order pharmacies, licensed pharmacists, and pharmacy technicians, has a duty to disclose all relevant information to both physicians and patients in providing professional advice, counseling, or services. This duty arises from the nature of the transactions involved in the provision of prescription drugs and the nature of the expert services provided in connection with the provision of prescription drugs. This duty also arises from the nature of the relationship among the parties - the treating physician, the dispensing pharmacy and its licensed professional pharmacist, and the patient, in which the patient must rely on the professional expertise and advice of the pharmacist and physician in the ingestion, application, and use of potentially hazardous pharmaceuticals.

21. By law, by professional standards, by custom, by reasonable public expectations, by marketing, by sales, and by web-based materials distributed by Medco Health, a special relationship of trust and confidence exists between patients and pharmacists.

22. Through Medco Health's internal training and education programs for its pharmacists, Medco Health encourages its pharmacists to use techniques in dealing with patients and physicians which are designed to induce reliance on that special

relationship of trust and confidence.

23. Medco Health represents to clients and to patients that, in addition to accurate prescription dispensing, it will provide the same professional pharmacy services which trained professional pharmacists perform at non-mail order pharmacies. These services, if properly performed, assure quality of care for patients through prevention of adverse drug interactions, verification of drug strength and dosage regimens, recommendation of alternative medically appropriate drugs, and monitoring patient outcomes.

24. Medco Health employs non-pharmacist employees to perform or assist in performing many of the tasks performed in other pharmacies by trained, licensed pharmacists. The proper use and supervision of these employees is governed by state pharmacy practice law.

II

Medco Health Cancelled and Destroyed Valid Patient Prescriptions, Cancelled and Returned Valid Patient Prescriptions, and Cancelled and Re-entered Other Prescriptions to Avoid Detection of its Contract Violations

____25. Medco Health has made a number of performance guarantees concerning the mail order pharmacy services it renders under contracts with state and federal plans, and private plans. Under these performance guarantees, Medco Health makes promises concerning the quality of the mail order pharmacy services rendered and must pay a penalty if it fails to meet some

performance measure or may receive a new contract award if it meets or exceeds performance measures.

____26. Medco Health caused its employees to permanently and wrongfully delete, cancel, or otherwise falsify prescription orders to appear to meet contractual performance guarantees. A number of prescription orders permanently deleted belonged to FEHBP patients.

27. In order to appear to achieve Medco Health's productivity rates and to meet contractual performance guarantees, Medco Health's employees, at its mail order pharmacies in Florida, Texas, Nevada, and Massachusetts, were directed by supervisors to permanently delete both prescriptions and open invoice reports so that it would appear that the mail order facilities had fewer delayed and unfilled prescriptions and Medco Health would avoid paying contractual performance penalties.

28. In certain cases, deleted prescriptions were returned to beneficiaries, or re-entered with a false date of receipt ("received date"), which was later than the actual received date.

29. Medco Health's employees falsified records and patients did not receive prescriptions that had been ordered or did not receive their prescription drugs on a timely basis.

30. Medco Health imposed quotas upon all professional personnel within mail order pharmacies to meet Medco Health's

cost objectives. These quotas are a direct cause of delayed prescriptions, and the subsequent improper cancellation of prescriptions.

31. All Vice President/General Managers ("VP/GM"), who are Medco Health's highest level managers at each mail order pharmacy, are measured against the operating cost of their pharmacies.

32. All pharmacists are measured on a quota system called "maximum quality per hour." This system measures how many prescriptions they review and resolve each hour of their work day at each work station. The "maximum quality per hour" system has harmful results:

- a. Pharmacists select the easiest prescriptions to read, review, and fill, known within Medco Health as "cherry picking." Pharmacists avoided "slut pans," that is, pans containing prescriptions which have been inside the pharmacy for long periods of time. Pharmacists avoid prescriptions which appeared to have issues of accuracy, reliability, and/or interaction requiring professional judgment and analysis.
- b. Pharmacy technicians perform functions which must by law be performed by pharmacists, or under a pharmacist's direct supervision.

- c. As a consequence of these productivity pressures, Medco Health employees made false records to show that they achieved their "maximum quality per hour." Some managers ignored evidence that employees were falsifying records in order to meet their own goals and some managers instructed employees to falsify records to meet their own goals.
- d. Medco Health senior officials were aware of and condoned false reporting by individual mail order pharmacies of turnaround times, false reporting of dates of receipt of prescriptions, false reporting of contacts with prescribing physicians, and improper cancellation of prescriptions.

33. Medco Health senior officials were aware of false reporting by individual mail order pharmacies of turnaround times, false reporting of received dates of prescriptions, false reporting of contacts with prescribing physicians, and improper cancellation of prescriptions.

- a. False reporting of turnaround times was tolerated because certain contracts contain penalty provisions for failure to meet turnaround times.
- b. False reporting of received dates assisted pharmacies in appearing to meet their turnaround

time requirements.

- c. False reporting of physician contacts helped pharmacies meet turnaround times, reduced processing costs for prescriptions, and allowed drug switching to occur.
- d. Cancellation of prescriptions assisted Medco Health in concealing its illegal conduct and allowed Medco Health to conceal or reduce its obligations to patients, to clients, and to the United States.
- e. Medco Health officials were aware of the significance of failing to provide prescription drugs on a timely basis. As the Senior Vice President for Mail Order Pharmacies stated in a memorandum, "By the very nature of the service we provide, delaying someone's medication by 14 or more calendar days has to raise concern as to the patient's health and safety."

34. Medco Health mail order pharmacies used various techniques to show that they were meeting turnaround time requirements when they were not and to reduce their obligations to patients, to clients, and to the United States.

35. The pressures placed upon Medco Health's VP/GMs of individual mail order pharmacies were intense. VP/GMs who stayed

with the company for five years could receive stock options valued at a million dollars, but relatively few VP/GMs lasted that long. VP/GMs who failed to meet their numerical goals were first subjected to humiliation before their peers in Monday morning conference calls known as "the Monday beatings."

36. The Executive Vice President of Medco Health conducted the Monday beatings for a number of years.

37. VP/GMs who continued to fail to meet their cost or turnaround goals were terminated and given 15 minutes notice to leave the building, never to return. VP/GMs often worked 70 hour weeks, and left needed management and supervisory positions vacant in order to keep costs down.

38. Medco Health employees and managers cancelled and destroyed thousands of patient prescriptions and delayed thousands of others, and made false statements and reports to cover up the illegal conduct.

39. Medco Health operated two mail order pharmacies in Tampa, Florida, known within the company as "Tampa I" and "Tampa II." Each of these pharmacies had difficulties in meeting the contractual turnaround time for prescriptions within the cost limitations set by senior management.

40. In these pharmacies, a number of improper and illegal practices developed to hide the failure to meet contractual turnaround time requirements. One practice was the cancelling of

prescriptions at or near the point where their contractual turnaround time expired, even though the prescription was valid and the patient had already been charged for the prescription.

41. A second improper and illegal practice was the use of a semitrailer parked behind the Tampa II pharmacy to hide purple pans (that is, pans containing prescriptions which were already out of time) whenever visitors from Blue Cross/Blue Shield came to the pharmacy. Employees would comb the floor early in the morning before such a visit, remove all purple pans, hide the purple pans in the trailer, and return the purple pans to the floor after the visitors had departed, in order to give the impression that the Tampa II pharmacy was meeting its turnaround requirements.

42. A third improper and illegal practice was the use of a turnaround team to remove overdue or soon to be overdue prescriptions from the floor of the pharmacy. The pans containing the prescriptions were stacked on the desk of one supervisor, or placed under her desk, or stacked on her chair, all in a location visible to any manager, supervisor, and employee who cared to look. These prescriptions were improperly cancelled, and destroyed, or reentered with a later date, to make it appear that the pharmacy was meeting turnaround time goals.

43. A fourth improper and illegal practice was the use of non-pharmacist personnel to adjudicate and dispense or cancel

patient prescriptions, without the legally and clinically required review by a licensed pharmacist.

44. A fifth improper and illegal practice was the intimidation of licensed pharmacists to discourage calls to physicians on prescriptions that were ambiguous, or required clarification of dosage or dispensing instructions. As a result of this intimidation, pharmacists in violation of state laws failed to refer prescriptions to the doctor call unit, resulting in faster turnaround but a significant risk of dispensing errors.

45. At various times, a significant portion of the Blue Cross/Blue Shield Association federal employee program mail order prescriptions were handled at the Tampa II pharmacy. The federal employee program prescriptions were also handled at the Tampa I pharmacy, and at other Medco Health mail order pharmacies.

46. The cancelled prescriptions would, in some cases, be destroyed. In other cases, the prescriptions would be reentered with a new receipt date. Both practices served to conceal from Medco Health's clients the failure to meet contractual turnaround time obligations.

47. These practices have gone on within various Tampa pharmacies within Medco Health for at least the last eight years, and have occurred at other pharmacies as well.

48. In 1997 Medco made a decision not to compare patient retail history with patient mail order history in performing drug

utilization review ("DUR") assessments, because of the failure of a Medco computer program. In 1998, Medco mandated nine months of retroactive DUR at Tampa II to cover the failure to perform this DUR at the time the prescriptions were dispensed. This large increase in workload caused delays in processing prescriptions. Medco Health did not want BCBSA to discover the nature and extent of Medco Health's failure to conduct appropriate DUR, or Medco Health's delays in filling prescriptions.

49. Upon information and belief, Medco management at Tampa II assigned the turnaround team the responsibility to cancel and re-enter prescriptions at the Tampa II facility with a later date, so the daily and monthly reports submitted to the BCBSA would falsely show that Medco was meeting its contract requirements for prescription turnaround time.

50. The supervisor assigned to manage the turnaround team at Tampa II in 1998 was the same supervisor ("turnaround team supervisor") who remained in charge of the turnaround team at Tampa II through February, 2001. This turnaround team supervisor wrote an e-mail to a subordinate detailing the turnaround team's "night drill," that is, the techniques to be used to appear falsely to have achieved turnaround time requirements. (This email is attached as Exhibit 1). Plaintiff believes and avers that improper cancellation of patient prescriptions to meet turnaround time has been a regular practice at Tampa II, not only

known to senior management within Medco Health, but encouraged by them in order to appear to meet contractual turnaround time requirements.

51. On May 15, 1998, a number of concerned pharmacists ("the concerned pharmacists") at the Tampa II mail order pharmacy approached Richard Clark ("President Clark"), President of Medco, while he was on a visit to the Tampa II pharmacy. The concerned pharmacists met with President Clark for fifteen minutes to advise him that the turnaround team supervisor at the Tampa II pharmacy had directed other employees to cancel and re-enter prescriptions so that Medco could appear to meet its turnaround time obligations under its contracts. The concerned pharmacists asserted that senior management at Tampa II was aware of and endorsed the actions of the turnaround team supervisor, so that the Tampa II facility could appear to be meeting its turnaround time obligations. The concerned pharmacists provided President Clark with the email attached as Exhibit 1 demonstrating the practice of cancelling prescriptions to meet turnaround time.

52. President Clark delegated responsibility for responding to the improper practices described by the concerned pharmacists to defendant Robert Blyskal, and advised the concerned pharmacists to address their concerns to defendant Blyskal.

53. The concerned pharmacists caused their union to present a detailed summary of techniques which Blyskal could use "to

review the suspect activity we discussed previously." In addition, the union presented to Blyskal lists of employees who may have been involved in the turnaround team, together with a list of witnesses.

54. Blyskal took no effective action to address the issues raised by the concerned pharmacists. Instead, he undertook an "analysis" that supported the statement by the Tampa II Vice-President/General Manager that improper cancellations resulted from a "miscommunication." When President Clark was again contacted by the concerned pharmacists, Blyskal assured the concerned pharmacists by letter on July 14, 1998 that he would address the concerns shortly, even though he had no intention of effectively investigating or reporting the results of an investigation, and never did so.

55. Blyskal knew that investigation of the Tampa II pharmacy practices, if conscientiously and thoroughly pursued by him in 1998, would lead to discovery that improper cancellations to meet turnaround time were common practice at the Tampa II mail order pharmacy, and had been known and authorized by him, and similar practices at other mail order pharmacies for which he also had responsibility were known and authorized by him, and could lead to loss of a significant portion of the mail order pharmacy business upon which Medco's profitability depended. Blyskal, upon information and belief, had personally caused the

submission of false or fraudulent documents in support of false or fraudulent claims relating to turnaround time, which he was responsible for investigating. Blyskal's failure to investigate, or to report what he knew about the improper cancellations resulted in submission of false monthly reports and a false certification in 1999.

56. Blyskal denied all knowledge of the 1998 allegations of improper cancellations to meet turnaround time when questioned about them during his CID examination. He repeatedly stated "I'm drawing a blank" or "I don't remember" when questioned about these matters during his CID examination on March 3 and 4, 2003. These answers were false, and made for the purpose of reducing a liability due the United States in violation of 31 U.S.C. 3729(a)(7). All records relating to that investigation have disappeared from Medco and defendant Blyskal stated in sworn testimony that he had no documents relating to that investigation. After being scheduled by agreement for further examination on May 1, 2003 Blyskal asserted for the first time, on April 29, that health concerns prevented him from providing further testimony.

57. In January 1999 defendant Robert Blyskal, selected defendant, Diane Collins as the Tampa II pharmacy "VP/GM". Ms. Collins was not a licensed pharmacist.

58. The supervisory employee identified to Blyskal by the

concerned pharmacists in 1998 as improperly cancelling prescriptions to meet turnaround time continued in charge of the Tampa II turnaround team, reporting to defendant Collins.

59. Upon her appointment at Tampa II in 1999, defendant Collins immediately began to push aggressively to meet her cost and turnaround goals. She adopted defendant Blyskal's "Monday morning beatings" approach in her daily management meetings at 9:30 each morning. She advised the supervisors that if they did not meet the company's goals, the Tampa II pharmacy would be closed and the work shipped to New Jersey.

60. In Ms. Collins' first year as VP/GM's of the Tampa II pharmacy, 11 supervisors left the Tampa II pharmacy.

61. Defendant Collins developed a system at Tampa II to allow her personally to create and to assist others in creating false records and reports to be submitted to the Blue Cross/Blue Shield Association for the FEP contract. She arranged to have access to the pharmacy computer operating system as the Director of Pharmacy Practice, even though she had never received any training as a pharmacist and had no license. With her access, she was able to alter prescription drug records after hours at the Tampa II pharmacy. Defendant Collins altered those records or instructed others to alter them whenever she believed it necessary to meet her turnaround objectives. Defendant Collins' conduct started in 1999 and continued at least until her

departure in January 2001.

62. In the summer of 2000, Medco Health developed improved internal reporting systems to capture turnaround information. These systems showed a problem with prescription turnaround time in a number of facilities, and pressure was placed upon defendant Collins to improve reported turnaround. In December 2000, a senior official at Medco Health directed that each patient who had a prescription at a pharmacy for more than 14 days was to be called by a supervisor from that pharmacy to advise of the delay.

63. Because patients were advised by Medco Health to expect their filled prescriptions eight days after the patient mailed the prescription, many patients who did not receive their prescriptions within eight days made WHIZMO (where's my order?) calls to Medco. Medco records show that there were over 400 such calls from a small sample drawn by Medco from Tampa II prescription orders in December 2000.

64. At the Tampa II pharmacy, the Director of Pharmacy Practice was instructed to make the telephone calls referred to in paragraph 62. She immediately realized that task was impossible because of the volume of calls required, and that she would be blamed for the failure to carry out these instructions.

65. In December 2000, the Tampa II Director of Pharmacy Practice called the Vice President of Professional Practices to complain about the defendant Collins' "management style."

66. During the winter of 2000-2001, Blue Cross/Blue Shield was soliciting proposals from other PBMs to take over Medco Health's mail order business, and asked for a proposal from Medco Health to retain the contract. Timeliness of prescription drug shipments was an important part of Blue Cross/Blue Shield's consideration. Senior management at Medco Health realized that, since the FEP contract was about to expire, and the bids for the new PBM contract were due on February 13, 2001, it was necessary to investigate and contain the allegations of misconduct.

67. Defendant Blyskal and other senior managers began their investigation that was designed to determine the extent of the problem at Tampa II, and to ensure that it did not implicate on anyone senior to defendant Collins.

68. On January 25, 2001, defendant Collins was interviewed by a senior manager of the Tampa II pharmacy and a Medco Health employment lawyer, with no prior experience in fraud and abuse investigations. Defendant Collins lied during that interview, denying all responsibility for the improper cancellation of prescriptions. Plaintiff believes and avers that Medco Health officials who interviewed her were well aware that defendant Collins was not being candid and forthright in her answers.

69. On January 30, 2001, notwithstanding her knowing false statements and the company's awareness of them, defendant Collins was offered a year's severance pay and full benefits for a year

as part of her termination package. She demanded and received an additional bonus of \$40,000 as part of her termination package.

70. The severance package provided to defendant Collins was intended by Medco Health to and did cause her to assume full responsibility for all improper conduct at the Tampa II pharmacy, to protect the Regional Vice President, the Senior Vice President of Pharmacy Operations, and defendant Blyskal from being implicated in the improper conduct, to refuse to speak with attorneys and agents of the United States voluntarily, and to assert her Fifth Amendment rights in response to virtually all questions during her examination pursuant to a Civil Investigative Demand issued by Attorney General John Ashcroft.

71. Defendant Collins has refused to speak with attorneys and agents of the United States voluntarily, and asserted her Fifth Amendment rights in response to virtually all questions during her examination pursuant to a Civil Investigative Demand issued by Attorney General John Ashcroft.

72. In February and March of 2001, in order to achieve maximum leverage over defendant Collins, Medco Health, while representing to her that the severance package was agreed to by the company, avoided sending an executed copy of the agreement to defendant Collins until she made statements to the company executives which contradicted her earlier statements, admitting to company executives total responsibility for the improper

conduct, and representing that no manager prior to her or senior to her had any knowledge or responsibility for the improper cancellations at Tampa II. Defendant Collins has refused to cooperate voluntarily with the federal investigation of these allegations.

73. On February 14, 2001, the senior managers involved in the investigation contacted the FEP account executive at Medco Health for the first time about the investigation. The FEP account executive contacted the Blue Cross/Blue Shield Association on February 15, 2001 to arrange a meeting about improper activity by defendant Collins and the turnaround manager. This meeting took place on February 16, 2001. On March 12, 2001, Medco Health presented an "analysis of issues regarding Merck Medco's Tampa II pharmacy" to the Blue Cross/Blue Shield Association.

74. This report was intended to place all responsibility for the improper cancellations of prescriptions on defendant Collins and the turnaround team manager and to prevent anyone from looking beyond Tampa II, or above defendant Collins or at Tampa II prior to Collins arrival. Medco Health and defendant Blyskal, over the next two years, undertook a series of actions including false and misleading statements and reports to prevent the United States from learning the full extent of the improper conduct at Tampa II, the involvement or knowledge of senior

managers at Medco Health about improper cancellations at Tampa II, and the full extent to which improper practices existed at other Medco Health pharmacies.

75. Medco Health has made a number of performance guarantees concerning the mail order pharmacy services it renders under contracts with state and federal plans. Under these performance guarantees, Medco Health makes promises concerning the quality of the mail order pharmacy services rendered and must pay a penalty if it fails to meet some performance measure or may receive a new contract award if it meets or exceeds performance measures.

III

Medco Health Made False Records of Contacts With Physicians about Drug Risks and Interactions ("DUR" Allegations)

76. Medco Health markets nationwide, and is mandated by law to provide to mail order pharmacy customers the service of pharmacists' monitoring of patient outcomes and accurate prescription delivery. In Medco Health's mail order facilities the Drug Utilization Review ("DUR") department is responsible for contacting physicians in order to review a patient's personal drug history to prevent drug-to-drug interactions and duplicate therapy. The DUR Department is also supposed to monitor improper dosing, drug-allergy interactions, drug-age combinations, and fraud and abuse.

77. At Medco Health's pharmacies, all DUR calls were formerly made by pharmacists who called physicians' offices to discuss potential drug-to-drug interactions, duplicate therapy, improper dosing, drug-allergy interactions, and drug-age combination.

78. Beginning in or about 1995, DUR was reorganized into "pods" with several non-pharmacist employees assigned to work with a single pharmacist. These employees call physicians to discuss DUR issues, and then connect the physician with the assigned pharmacist to confirm the substance of the DUR call. These employees usually have no prior training in pharmacy services other than limited on-the-job training.

79. Non-pharmacist DUR employees are not supervised by the pharmacists with whom they work. Instead, they report directly to non-pharmacist supervisors who are in charge of maintaining DUR call quotas and productivity.

80. Each member of the pod is provided a quota of hourly calls which each employee must make. The employees are then required to record information about these calls. The quotas each DUR employee must make are part of Medco Health's overall efforts to maintain and increase productivity goals.

81. Pods that are slow or fall behind their quotas are reprimanded or otherwise pressured to meet their call quotas. DUR employees are then reprimanded or fired if they fail to

maintain their quotas.

82. DUR employees: a) fabricated physician call records to maintain hourly call quota rates; b) completed physician calls without ever having pharmacists verify the information with the physician's office; c) changed prescriptions without a pharmacist's intervention; and d) falsified records to indicate DUR calls were made to physicians when in fact these calls were not made.

83. Medco Health's efforts to limit DUR services in its mail order pharmacy operations can harm the vital role pharmacists play in making sure that drug interactions and prescription changes are being monitored. As a result, patients receiving these prescriptions are placed at risk, including patients who participate in government prescription benefit programs.

84. The provider reimbursement Medco Health receives is based on properly performed DUR-related services. To the extent these services are not provided pursuant to law and contract, Medco Health submits false claims to the government.

IV

Medco Health Failed to Contact Physicians on Ambiguous or Unreadable Prescriptions ("Doctor Call" Allegations)

85. Medco Health represents to its customers that it operates at the highest level of care and professional standards, and that there is no safer dispensing environment than exists at

Medco Health.

86. Each of the Medco Health mail order pharmacies used a Doctor Call Department that contacted physicians to confirm drug strength and dosage, completed inaccurate or questionable drug or patient information, and verified prescription changes.

87. In the past, all Medco Health mail order Doctor Calls were made by pharmacists, who contacted physicians to verify prescription strength, make corrections to inaccurate prescriptions, and check on prescription changes and confirm scheduled drug prescriptions.

88. Beginning in or about 1995 Medco Health reorganized the Doctor Call Department in mail order pharmacies and reduced the involvement of pharmacists.

89. The Doctor Call Departments are now comprised of pods containing non-pharmacist employees and one pharmacist. Each employee in the pod has an individual quota of 20 to 25 calls to physicians per hour, including the time spent recording the results of these calls. The pharmacist, meanwhile, is added to the employee's call to the physician only at the end to verify information on the prescription. This means that pharmacists are frequently handling an unmanageable number of calls.

90. The unmanageable number of calls results in the failure by pharmacists to consult readily available on-line patient profiles, thereby potentially compromising patient safety.

91. Doctor Call employees, like DUR employees, are not supervised by the pharmacists with whom they work. Instead, they report directly to non-pharmacist supervisors who are in charge of maintaining Doctor Call quotas and productivity.

92. As a result of the environment created by Medco Health's pressures to meet aggressive quotas and maintain financial productivity, Doctor Call employees: a) fabricated Doctor Call records to maintain hourly call quota rates; b) completed physician calls without having supervising pharmacists verify the information with the physician's office; c) changed prescriptions without a pharmacist's intervention; and d) falsified records to indicate Doctor Calls were made to physicians when in fact these calls were not made.

93. Doctor Call employees who complain, or who attempt to slow down the process to ensure that calls are being done accurately, are subject to harassment and disciplinary action and termination.

94. Medco Health's deliberate efforts to limit the Doctor Call services in its mail order pharmacy operations have in some instances resulted in damage to the vital role Doctor Call pharmacists play in making sure that prescription changes are being monitored and drugs correctly dispensed. The lack of pharmacists' involvement directly places at risk those patients who receive these prescription drugs, including patients who

participate in government prescription benefit programs. Other patients never receive their filled prescription medications because Medco Health failed to comply with contractual doctor call attempt requirements.

95. As a result of the foregoing, Medco Health's clients and patients are being charged for services not rendered or that are rendered well below even marginally adequate professional standards. Claims submitted for pharmacy services which do not meet minimum professional standards are false or fraudulent claims.

V

Medco Health Knowingly Caused its Customer Service Representatives to Make False Statements to Patients ("Customer Service" Allegations)

96. Medco Health represents to its clients, including the government, that its mail order pharmacy services include a customer service department staffed by licensed pharmacists 24 hours a day, seven days a week, to answer questions from patients.

97. The operation of the Customer Service Department is included as a portion of the fees Medco Health charges its customers, including state and federal mail order programs. The contracts provide financial incentives for Medco Health to exceed certain performance measures as well as penalties for not meeting these measures. For example, the FEHBP contract specifies that

customer service calls will be answered within certain time frames, and that no more than two percent of customer calls each week will receive a busy signal (known as "call blockage").

98. Customer service representatives and pharmacists responding to patient inquiries were directed by Medco Health to provide false or misleading answers to patients' inquiries.

99. These false or misleading statements include:

- a. Representing that a patient who was unhappy after being switched to a new medication would be required to call the physician personally to obtain a new prescription for the original drug, even though this was not true.
- b. Representing to a patient who had been switched to a new drug that Medco Health was just following the doctor's order, when Medco Health had requested the switch to increase its profits.
- c. Representing that prescriptions had never been received, when they had been received and improperly cancelled.
- d. Failing to disclose Medco Health's alleged policy of paying for increased health care costs resulting from switches.
- e. Representing that patients who wanted to switch back to their original prescription were required

to pay two co-pays, when this was not true.

- f. Representing that in the opinion of the pharmacist all the generic drugs sold by Medco Health were always "just as good" as brand name drugs, even where the pharmacist did not believe the representation with respect to some generics.

100. Medco Health customer service call centers are responsible for handling complaints and questions received from mail order patients around the country. In addition, each mail order pharmacy responds to telephone inquiries from customers.

101. These acts have caused (and may continue to cause) patient medical harm and considerable financial harm to patients and clients paying for these prescriptions, including programs sponsored by the state and federal governments.

102. As a result of the foregoing, Medco Health's patients and clients have been and are being charged for services not rendered or that are being rendered well below even marginally adequate professional standards. Medco Health has submitted and continues to submit false claims to the government when it bills for prescriptions without performing such services.

VI

Medco Health Improperly Delivered Fewer Pills than it Reported and Charged to Patients and Clients ("Shorting" Allegations)

103. Medco Health bills federal and state health insurance plans nationwide for prescription drugs shipped to patients without accurately ensuring that the correct number, strength, dosage, and type of drugs are in the correct bottle.

104. Medco Health has delivered to patients prescription drug bottles containing fewer pills than shown on the label, and fewer pills than were billed to clients and patients, a practice known as "shorting."

105. Shorting is known to occur from time to time with automated pharmacy equipment. Shorting occurred more frequently when a new automated pharmacy was brought on line.

106. When the Las Vegas pharmacy was brought on line, there were significant shorting problems from the automated "Baker Cells system," the machinery which distributes pills to prescription bottles.

107. Shorting also occurs with pills in poor physical condition, with poorly maintained equipment, and with changes in heat or humidity.

108. Medco Health has known of shorting problems in its automated mail order pharmacies since 1996, but has continued to ship and bill for shorted prescriptions since that time.

109. The automated Baker Cells system malfunctions and shorts prescriptions. Medco Health initially attempted to

correct the inaccurate pill counts by establishing a checking area where pharmacists were charged with checking every prescription in every package being mailed to customers.

110. Medco Health was concerned that this checking for inaccurate and shorted prescriptions by pharmacists was very expensive, and was driving up the cost per prescription. As a result, Medco Health soon discontinued altogether the checking procedure for prescription drug count accuracy.

111. Medco Health's solution to the problem of shorting was to ignore dispensing problems and drug shortages. As part of its plan to mask the drug shorting issue at the Las Vegas pharmacy, Medco Health discontinued its previous policy on open publication of error rates within the pharmacy so that pharmacists' understanding of the company's error rates was eliminated. (Prior to this time, Medco Health each day posted the previous day's error rate.)

112. In order to maintain production quotas to get the products out of the door, Medco Health relies on Customer Service Representatives to take care of pill shortage problems. Customer Service Representatives were told to tell customers that their shorted prescriptions were done accidentally or by mistake, even though Medco Health knew that prescription drugs being mailed out on a daily basis had been shorted.

113. When Customer Service employees complained about the

high volume and severity of the shorted prescriptions, Medco Health supervisors instructed them that they were forbidden to talk about the Company's operational difficulties and that Medco Health would be regularly taping Customer Service Department telephone calls to make sure no employee disclosed these problems.

114. The Customer Service areas regularly received "horror stories" from customers who had received incorrect mail order prescription drugs, including shorted prescriptions, the wrong drugs, incorrect dosage, crushed pills, and the incorrect number of days supply.

115. Pharmacists who consistently caused slow-downs to avoid shorting problems or failed to meet production goals were subject to disciplinary action, including termination of employment.

116. The shorting was not reflected on the prescription bottles to inform patients, nor were treating physicians notified that their patients were receiving inaccurate tablet counts.

117. Medco Health was aware that dispensing problems existed at the Las Vegas, Nevada NDP pharmacy, because pharmacists complained to supervisors, managers, and Medco Health's Ombudsman.

118. Medco Health corporate management held a meeting with pharmacists in December of 1996. During this meeting, Medco Health admitted that the Las Vegas pharmacy was experiencing drug

shorting problems. Management also advised pharmacists that Medco Health's policy is to allow shorted prescriptions to be shipped to patients.

119. Following the meeting at the Las Vegas pharmacy, in a memorandum from Medco Health to NDP pharmacists dated December 26, 1996, the company memorialized the policy directive announced at the meeting. According to this memorandum, "short counts" of three or less were deemed "acceptable."

120. Medco Health thereafter discouraged pharmacists and other employees' discussion of the drug shorting topic. Pharmacists who complained were advised that they had the option to quit.

121. Patients from all over the country frequently called Medco Health Customer Service representatives to complain about shorted prescriptions.

122. Shorting prescriptions continued after this time to the present at the Las Vegas pharmacy.

123. Shorting prescriptions occurs in other Medco Health mail order facilities.

124. Medco Health did not alter, adjust or correct its billings to reflect shorted prescriptions or other dispensing errors. As a result, millions of dollars have been and are being paid by the states and the federal government to Medco Health for prescription drugs which were not and are still not being

dispensed to patients. In addition, patients were required to obtain authorization from physicians and pay community pharmacies out of their own pockets for the shorted pills.

VII

Medco Health Created False Records Concerning Quantity of Drugs Delivered and Dispensing Errors

125. Medco has an obligation under various contracts with federal health plans and other clients to meet certain mail order pharmacy performance standards. For example, the FEP contract, at relevant times, required that 97.5% of new prescriptions and prescription refills be filled within five business days of receipt, and 96% of refill prescriptions received by telephone, internet, or from doctors' offices be filled within two business days.

126. Medco Health represents that, in addition to accurate prescription dispensing, its mail order facilities will fill prescription orders in a timely manner and in accordance with all contractual performance guarantees.

127. Under these contractual performance guarantees, Medco Health: (1) must pay performance penalties if it fails to meet its performance guarantees; and (2) may receive awards if it meets or exceeds its performance guarantees.

128. Medco Health has failed to disclose shorting in performance reports relating to error rates despite the fact that

it knew of the shorting problems.

129. Medco Health regularly falsified reports of class A error rates (that is errors which resulted in improper quantities of prescription drugs being sent to patients) in order to improve its reported contract performance at the Las Vegas pharmacy.

VIII

Medco Health Made False Records Concerning Required Calls to Physicians In Order to Fill and Bill for Prescriptions Not Authorized by Physicians

130. It was the practice and custom of a number of employees at the Dallas/Fort Worth mail order pharmacies to create records showing that physicians had been contacted in connection with doctor call, DUR, managed care, and other required physician contacts, when no such contact had taken place.

131. The issue of records falsification at the Dallas/Fort Worth pharmacy was raised in questions directed to defendant Blyskal during his March 2003 examination by the United States pursuant to a Civil Investigative Demand issued by Attorney General John Ashcroft. Defendant Blyskal had been the Vice President/General Manager of the Dallas pharmacy. Defendant Blyskal's attorney refused to permit him to answer any questions concerning records falsification at the Dallas/Fort Worth pharmacy.

132. Immediately after defendant Blyskal's examination, Medco Health sent a team of attorneys and auditors to the

Dallas/Fort Worth mail order pharmacy. They limited their review to February 2003 records, and discovered a significant number of prescriptions where the pharmacy showed a telephone contact with a physician's office at a given date and time but the telephone records showed no such contact.

133. Each prescription which was filled, shipped, and charged was illegal under governing law, and therefore false or fraudulent if it was not actually preceded by the physician communication documented in the patient record.

134. Medco Health has never disclosed to patients, third-party payors, or the United States detailed results of this Dallas/ Fort Worth review. Plaintiff believes and avers that nine employees were disciplined or terminated as a result of the review. No notice was ever given to the patients or the prescribing physicians that Medco Health had falsified these records.

135. The United States believes and avers that Medco Health intentionally limited its review to February 2003 to limit its exposure for an illegal practice which has existed at multiple pharmacies within Medco Health for many years.

136. Medco Health knowingly made a false statement in support of its false claims when it publicly reported to the *Pink Sheet* in July 2003 that the issues at the Dallas/Fort Worth pharmacy were discovered as the result of a "routine audit." In

truth and in fact, Medco Health's routine audits had completely failed to disclose or report these practices.

IX

Medco Health Made False Statements to Favor its Parent Company, Merck and other Manufacturers' Products over less Expensive, Safer, And/or More Effective Drugs ("Drug Switching" Allegations)

137. Notwithstanding its obligation to disclose information to patients and physicians in order to assure that prescription drug transactions among pharmacists, patients, and physicians are properly conducted, Medco Health undertook a program and course of conduct designed to prevent its professional pharmacists from disclosing relevant, important information to physicians and patients, and to affirmatively compel them to present a false or misleading impression. This course of conduct was intended to and did interfere with the legitimate decision-making authority of physicians and patients, and denied them material information upon which to make decisions concerning patient care. Medco Health's conduct included the following:

- a. The creation of "independent pharmacy and therapeutic ("P&T") committees to oversee the development of formularies." American Medical Association policy permits use of a formulary model in an out-patient setting, provided it operates under a P&T Committee whose recommendations must have the concurrence of a

majority of physicians affected by the formulary, and must meet standards comparable to hospital and staff settings. The P&T Committee at Medco Health meets neither of these standards.

- b. Obtaining approval from the P&T Committee for certain formulary decisions and drug switching programs on the basis of false or misleading information to the P&T Committee members. This false and misleading information included, but was not limited to, information about the cost of target and preferred drugs, the nature of the contact between pharmacists and physicians' offices, and the safeguards used by Medco Health in order to assure that full and complete information is presented to prescribing physicians prior to any judgment about the appropriate course of treatment for a given patient.
- c. Refusing to allow pharmacists to discuss the drug switches with any patients prior to a switch, in violation of each pharmacist's duty under state law to provide appropriate counseling to patients about their prescriptions.
- d. Making false statements to patients and physicians concerning the switches, the reasons for the

switches, and the effect of the switches, in order to induce them to approve the switch, or to withdraw objections to the switch.

- e. Developing protocols and training pharmacists in protocols designed to discourage patients' attempts to switch back to their original drugs after receiving a new prescription in the mail.
- f. Falsely representing to patients and physicians the "therapeutic equivalence" of specific pairs of drugs (e.g. Cenestin and Premarin).
- g. Failing to pursue cost reduction opportunities with certain manufacturers, in return for payment of inducements by their competitor manufacturers, including Merck, to Medco Health.
- h. Promoting drugs which will remain on patent for long periods of time, and switching patients from drugs which will be subject to generic competition and cost reductions in the near future.
- i. Refusing to provide information to physicians to assist them in making informed judgments about appropriate drug choices.
- j. Switching patients from drugs with a generic equivalent to drugs without a generic equivalent.

A. Medco Health Operated its "Managed Care" Department to Switch Patient Prescriptions

138. Medco Health represents that its mail order pharmacies have Managed Care Departments whose stated purpose is to contact physicians to monitor clinical outcomes and maintain compliance with drug formularies. In truth and in fact, Managed Care Departments do not manage care; they manipulate patient drug selection and place patient health at risk to enrich Medco Health.

139. A formulary is supposed to be a list of FDA-approved prescription drug medications, created to assist in maintaining the quality of patient care and containing costs for the patient's drug benefit plan. Prescribers are requested to refer to the formulary when selecting prescription drug therapy for plan members. Medco Health provides copies of its formulary to doctors, patients, and pharmacists to aid prescribers' adherence to the formulary.

140. Medco Health represents to health plans that its "Preferred Prescriptions Drug Formulary" list (the "preferred list") is reviewed by an independent P&T committee, and will achieve quality care and cost containment objectives for health plans. However, this formulary favors many expensive Merck brand drugs, including Zocor, Mevacor, Prinivil, Vasotec, Cozaar, Hyzaar, Prinzide, Vaseretic, Pepcid, Fosamax, Timoptic, Trusopt, Cosopt, Chibroxin, Singulair, Proscar, Noroxin, Sustiva,

Crixivan, Maxalt, Clinoril, Dolobid, and Vioxx, over other manufacturers' less expensive drugs. The preferred list contains most of the drugs manufactured by Merck that are susceptible to mail order pharmacy dispensing (i.e. vaccines are not included).

141. In reality and practice, the role of Medco Health's Managed Care Department is to switch patients from a currently prescribed drug to a target drug. The target drug is either a Merck manufactured formulary drug or a drug manufactured by a competitor company with whom Medco Health has entered into a rebate contract.

142. The primary reason Medco Health switches drugs is to enhance its revenue regardless of health plan costs, or of any potential adverse or life-threatening clinical outcomes to patients associated with the switch.

143. To increase drug switching success rates, Medco Health pressures employees and pharmacists working in the Managed Care Department to obtain switches of drugs, and requires employees and pharmacists to meet a quota of calls to physicians and others each hour. Medco Health monitors closely the rate at which attempts to switch drugs are successful. If employees fail to meet the quota, they are subject to disciplinary action and employment review.

144. Medco Health employees are provided with a script that specifies how employees should pitch proposed drug switches.

145. At times, calls to physician offices are preceded by a fax sent to the physician's office from a Medco Health corporate office requesting that the physician switch to the Medco Health targeted drug.

146. Patient and physician complaints about switching prescriptions by the Managed Care Department are common. These complaints have been communicated in writing to Medco Health. Medco Health routinely ignores these complaints including the health risks associated with inappropriate drug switches.

147. Medco Health does not follow-up with patients who have been switched to a different drug, and fails to monitor the outcome of these drug switches.

148. Drug switching based on undisclosed financial reasons may endanger the health or life of the patient whose drug was switched at the initiation of Medco Health and results in increased health care costs, in some cases to patients and to the United States.

149. Each of the practices referred to above occurred as a result of a conscious corporate policy and specific corporate direction.

B. Medco Solicited Payments to Switch Patients' Prescriptions

150. Medco Health knowingly solicited payments from certain pharmaceutical manufacturers to induce the sale of their products. These payments were made in the form of rebates,

patient conversion payments, market share movement payments, and disease management program payments. In addition, certain pharmaceutical manufacturers contracted with Medco Health for nominally priced products.

151. Medco Health received substantial sums from pharmaceutical manufacturers, including Merck, in order to favor the manufacturers' products over different chemical compounds in the treatment of certain disease conditions. Medco Health agreed with certain manufacturers, including Merck, to favor and advocate the products of those manufacturers in dealings with its clients and patients, and to advocate switches to those favored products by physicians, even where the other ("disfavored") products were cheaper to patients or plans, or more effective, or had fewer side effects, or had less expensive generic equivalents or alternatives to the favored drugs. Medco Health advocated drug switching even in patients who had been stable on the disfavored drug for long periods of time, or previously had bad outcomes or side effects with the preferred drug. Despite its representations about its expertise in the management of patients' pharmaceutical care, Medco Health made no effort to determine the consequences to patients following switching from one chemical compound to another. Even when Medco Health received complaints from patients about the consequences of the switch, Medco Health made it difficult to report the complaint,

and made no systematic effort to analyze the information provided by patients and physicians to determine whether the switches its pharmacists were advocating presented risks to patients, or resulted in a need for increased care.

152. At times the preferred products were more expensive than the originally prescribed drugs and increased the cost for treatment of that patient to the government and to patients.

153. Some pharmaceutical manufacturers also paid Medco Health an agreed upon amount for each successful conversion of a patient's non-preferred drug to a preferred drug. None of these payments were disclosed to the physicians who were requested to authorize the switch, nor were they disclosed to the patients whose prescriptions were being changed. The proposed switches were presented to the physicians as "calling on behalf of the health plan," even though the switches were advocated by the pharmacist for the financial benefit of Medco Health.

154. Medco Health also entered into agreements with manufacturers for nominally priced products including, Hytrin and K-tabs. At times the net price to Medco Health of these nominally priced products was one cent. The government and patient were charged based upon a percentage of Average Wholesale Price for Hytrin and K-tabs.

155. Medco Health solicited and received money from manufacturers to support disease management programs including

programs for sinusitis and H. Pylori.

156. In order to obtain favorable consideration in connection with their subcontract to supply prescription drugs to Medco Health in connection with prime contracts, certain pharmaceutical manufacturers made improper payments to Medco Health.

C. Medco Received of \$439.7 Million in Order to Favor Merck Drugs During 2001

157. Medco received payments (or imputed payments) of **\$439.4** million during 2001 from Merck to favor Merck's products over those of its competitors. In addition, Medco Health has agreed in Section 6 (Best Efforts) of its Merck agreement that it will refrain from taking any action which directly or indirectly causes any of its plans to discourage or restrict the use of Merck products, or to encourage the use or exchange of any competitive products in the same therapeutic category, unless for clear and objective safety reasons based on valid scientific data or FDA directive. Due to the conditions of its relationship between Merck and Medco Health, Medco Health is unable to present objective information, advice, or opinions to patients, plans, physicians, or consultants. The amounts of these payments, and the contractual obligations resulting from these payments, were not disclosed to Medco Health's clients, including the government and its prime contractors, and were made with the intention of influencing Medco Health's judgment about which drugs to

recommend to its clients about which drugs they should prefer. Medco Health specifically represented that it was independent of Merck in its services to its clients.

X

Medco Health Made Improper Payments to Health Plans with Federal Contracts, to Be Selected as the Plan PBM ("Kickbacks to Health Plans" Allegations")

158. In 2001, Medco Health entered into negotiations with a health plan ("the health plan") to obtain its pharmacy benefit management contract effective January 1, 2002. This contract was for services to be provided to, among others, 60,000 Medicare beneficiaries and numerous federal employees and dependents.

159. In order to obtain favorable consideration of its bid for the contract, Medco Health paid the health plan \$87.4 million in cash in the last two quarters in 2001. These payments were represented as reimbursement for systems and other costs in connection with the transition to Medco Health (\$4.5 million) and "an alliance agreement . . . under which the health plan develops and provides certain historic and current information and furnishes strategic consultative and other services . . . over a five year period . . ." (\$82.9 million), but were in fact intended to improperly influence the awarding of the pharmacy benefit management subcontract.

160. Plaintiff believes and avers that the payment by Medco Health to the health plan to improperly obtain favorable treatment was knowing. In the summer of 2000, Medco Health

approached the United States Attorney's Office in Philadelphia to complain that one of their competitor PBMs was attempting to obtain PBM contracts by improperly providing items of value to plan administrators, who were in a position to award or continue PBM contracts.

161. The alliance agreement was intended by both Medco and the health plan to be an integral part of the PBM agreement, and to pay the health plan for patients referred to Medco's mail order pharmacies, including its Florida-licensed mail order pharmacies. Medco was aware that the health plan required cash during the fourth quarter of 2001 to honor its commitments to repurchase shares of the health plan stock.

162. Upon information and belief, additional payment in cash and in services have been made to other health plans to induce the plans to select Medco Health as a pharmacy benefit management subcontractor, or to retain Medco Health as a pharmacy benefit management subcontractor, where the prime contract is between the United States and a health plan.

163. Medco Health, a subcontractor, in providing a kickback to the health plan and other health plans, violated the Anti-Kickback Act, 41 U.S.C. §§ 51, 53(1).

164. The health plan and other plans are prime contractors. They entered into a prime contract with the United States to supply services. Medco is a subcontractor because it is a

corporation that has offered to furnish services under a subcontract in connection with such a prime contract.

165. The direct payment of \$87.4 million to the health plan by Medco to obtain the PBM contract was for an improper purpose and constitutes a kickback. The improper purpose is favorable treatment in connection with a subcontract relating to a prime contract which has been entered into with the United States.

XI

Each of Medco Health's False Claims Was "Knowingly Submitted" Because Medco Health Had No Effective Corporate Compliance Program to Detect and Prevent False Claims

166. Medco Health acted knowingly, as that term is used in the False Claims Act, 31 U.S.C. § 3729, that is, with reckless disregard or deliberate ignorance of the truth or falsity of information it submitted to the United States and its contractors in support of its claims.

167. This reckless disregard or deliberate ignorance arose from the following actions and course of conduct by Medco:

- a. Medco Health's Board members and officers failed to satisfy their obligation to assure "that information and reporting systems exist in the organization that are reasonably designed to provide to senior management and to the Board itself timely, accurate information sufficient to allow management and the Board, each within its

scope, to reach informed judgments concerning the corporation's compliance with the law. . . ." In Re Caremark, 698 A.2d 959, 969 (Del. Ch. 1996).

- b. Medco Health failed to implement a corporate compliance program which satisfied the requirements of proper corporate practice and Delaware law.
- c. The compliance program in place at relevant times was not reasonably capable of reducing the prospect of misconduct. Most employees were either entirely unaware of the existence of such a program, or were not familiar with its details.
- d. There were no specific high-level personnel within Medco with direct responsibility for overseeing compliance, with direct access to the CEO and Board of Directors.
- e. There was no compliance officer within Medco Health with responsibility for independently investigating and acting on matters related to compliance, including the flexibility to design and coordinate internal investigations. Rather, it was the practice to assign responsibility for investigations to executives within whose area of responsibility the alleged wrongdoing occurred.

- f. There were no regular reports to the Board concerning internal investigations.
- g. There was no effective, timely communication to employees about the program.
- h. There were no effective methods of monitoring, auditing, or reporting on compliance.
- i. There was no effective anonymous hotline.
- j. There was no effective protection of whistleblowers.
- k. There was no consistent enforcement through corrective actions; rather, certain management, supervisors, and employees who engaged in illegal activities were rewarded with substantial severance packages in return for protecting more senior executives, and agreeing not to report violations to outside investigators.
- l. There were no systems to assure reasonable steps to respond to reported offenses, including detection of violations and investigation of violations.
- m. Such reporting of violations as did occur was false and misleading, and designed to hide the extent of the violations, the effect on patients, the role of senior executives in the violations,

and the need for further investigation of violations.

- n. There was no effective code of ethics as that term is used in SEC Release Nos. 33-8177 and 34-47235.
- o. There was inadequate due diligence to support the representation under 18 U.S.C. § 1350 set forth in the May 14, 2003 certification by a Medco Health board member that "any fraud, whether or not material, that involves management" had been disclosed.

XI

Illegal Conduct of Defendant Robert J. Blyskal, Executive Vice President of Medco Health

168. Defendant Robert J. Blyskal was, at relevant times, the Vice-President of Medco Health's mail order pharmacy in the Dallas/Forth Worth metropolitan area, and later Senior Vice-President for operations of Medco Health (until April 2002). In April 2002, he was promoted to the position of Executive Vice-President of Operations and Technology, the second highest position in Medco Health.

169. Defendant Robert Blyskal was also, between 1998 and June 2003, President of each of the defendant corporations which operated the mail order pharmacies at Tampa I, Tampa II, Tampa III, Dallas/Fort Worth, and Nevada. As president, his responsibilities were "to be able to sign as president in terms

of employee terminations, in terms of purchase, that sort of thing."

170. Defendant Blyskal was responsible for approving Diane Collins' termination package at Tampa II, and signed the severance agreement with defendant Collins. Blyskal had recommended Collins for the position of Vice-President/General Manager of the Tampa II pharmacy, as well as several prior promotions.

171. Defendant Blyskal ignored his legal duties as president and director of each subsidiary corporation, and the corporate formalities required by state law.

172. Defendant Blyskal was interviewed by the United States Attorney's Office on April 26, 2001. During his interview, Blyskal was specifically advised that an intentional false statement to a United States employee in the course and scope of his duty was a crime. He responded "I understand." During the interview, Blyskal's answers were evasive, and in some cases actually false:

Q. Do you believe within Merck-Medco that your turnaround statistics accurately reflect what is actually going on in the pharmacy?

A. Yes.

At the time Blyskal gave this answer, he had participated in interviews, and received a report showing that Merck-Medco's turnaround reports were false.

Q. Have there been situations to your knowledge where the

turnaround information which the company presents to customers or clients, does not accurately reflect what is going on in a any particular pharmacy?

A. Are you say are we submitting a report that I know to be false: The answer to that is no.

This answer was evasive and misleading. Blyskal clearly was aware of situations where the turnaround information presented to customers or clients did not accurately reflect what is going on in any particular pharmacy.

Q. There's a tense issue. Has Merck-Medco submitted reports to customers or clients which later turned out to be false?

A. Not to my knowledge, no.

This answer was false.

Q. Have there been employees who have been disciplined for preparing reports concerning turnaround times or out the door times which later turn out to be false or inaccurate?

A. We have an issue that we're currently dealing with where there's been some allegations to that impact and we're in the process of investigating that. We have never knowingly created reports to falsify that.

This answer was intended to create a false impression; at the time it was given, Blyskal knew that two employees had been terminated and that reports had been submitted by Medco that were false or inaccurate.

173. Defendant Blyskal was examined pursuant to 31 U.S.C. § 3733(h)(1), based upon service of a Civil Investigative Demand executed by Attorney General John Ashcroft, on March 3 and 4,

2003. During that examination, Blyskal made false statements in support of false claims to the United States, and made false statements to conceal or reduce Medco's liability to the United States, by denying knowledge of any prior allegations of improper prescription cancellation before January 17, 2001.

174. Each of these false statements was made to conceal, avoid, or decrease an obligation to pay the Government, and was made in support of a false claim.

175. The United States incorporates by reference the allegations contained in paragraphs 1 through 174 above as if set forth fully in each of the Counts below.

COUNT ONE

FALSE CLAIMS ACT

176. Medco Health and its alter ego mail order pharmacies knowingly presented, or caused to be presented false or fraudulent claims to the United States for payment or approval. Claims submitted by Medco Health and its mail order pharmacies were false or fraudulent because Medco Health failed to abide by laws, rules, regulations, and professional standards governing pharmacy practice, and consumer protection laws. These failures amount to material misrepresentations made to obtain a government benefit, that is, payment for prescriptions not authorized by law and contract.

177. Medco Health knowingly made, used, or caused to be made

or used, false records or statements to get false or fraudulent claims paid or approved by the government.

178. Medco Health knowingly made, used, or caused to be made or used, false or fraudulent records or statements to conceal, avoid, or decrease an obligation to pay or to transmit money or property to the Government.

179. Defendants Robert Blyskal and Diane Collins knowingly caused false or fraudulent claims to be presented for payment or approval to the United States.

180. Defendants Robert Blyskal and Diane Collins knowingly caused false statements or records to be created or made in support of false or fraudulent claims presented for payment or approval to the United States.

181. Defendants Robert Blyskal and Diane Collins knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease Medco Health's obligation to pay or to transmit money to the United States.

182. The claims which are the basis for this cause of action were submitted to a variety of federal contractors, including but not limited to the Blue Cross and Blue Shield Association for payment for services rendered to federal beneficiaries, or were certifications submitted by Medco Health each year "with respect to the amounts that they have charged to the contract." The United States reimburses the Blue Cross and Blue Shield

Association and other federal contractors for a portion of the money which is requested or demanded by Medco Health, and receives funds arising out of payments due from Medco Health as rebates, refunds, or contractual penalties.

WHEREFORE, the United States requests entry of judgement in its favor, and against each defendant, in an amount equal to triple the damages sustained by reason of that defendant's conduct, together with civil penalties as permitted by 31 U.S.C. § 3729.

COUNT TWO

PUBLIC CONTRACTS ANTIKICKBACK ACT

183. Medco Health knowingly offered to provide and provided or paid money, things of value, and compensation to a prime contractor in order to improperly obtain favorable treatment in connection with a subcontract relating to a prime contract with the United States for supplies, materials, or services.

184. Medco Health knowingly solicited and attempted to solicit money and things of value from pharmaceutical manufacturers seeking to provide pharmaceuticals to federal beneficiaries in order to improperly obtain favorable treatment in connection with a prime contract with the United States.

WHEREFORE, the United States requests entry of judgment in its favor and against defendant Medco Health in an amount equal to twice each kickback provided or solicited by Medco Health.,

together with a penalty per kickback as provided by 41 U.S.C. § 55(a)(1)(B).

COUNT THREE

UNJUST ENRICHMENT

185. As a result of the conduct set forth in this complaint, Medco Health was unjustly enriched at the expense of the United States.

WHEREFORE, the United States requests entry of an order directing Medco Health to pay over to the United States the amount by which it was unjustly enriched at the expense of the United States.

COUNT FOUR

ACTIVE AND CONSTRUCTIVE FRAUD

186. In the operation its licensed pharmacies, and the provision of prescription drugs and the services of its employee professional pharmacists, Medco Health has a position of superior knowledge and skill concerning the medications it dispenses, and their risks, costs, and benefits, to the patients who rely upon it. Pharmacists as a profession are required to have, and do have a relationship of high trust and confidence with patients, and Medco has emphasized the special nature of that relationship in its marketing materials and communications with patients, clients, and the general public. Each pharmacist has the responsibility to use his or her best professional judgment in

the interest of the patient whose prescription he is handling. Medco Health directs, encourages, and requires its pharmacists to engage in conduct which, taken as a whole, collectively violates the trust and confidence of patients and their physicians, deceives others, and injures the public interest through deception, breach of trust, or failure to disclose information necessary to make informed choices.

187. The United States makes payments for pharmaceutical services to Medco Health on the implied condition that the pharmacies and the professional pharmacists involved have complied with their professional, legal, contractual, and voluntarily undertaken responsibilities. To the extent that Medco Health and its employees have failed to do so, both the patients and the United States have been harmed.

WHEREFORE, the United States seeks entry of judgment in its favor and against Medco Health in an amount equal to the loss incurred as a result of the constructive fraud by Medco Health.

COUNT FIVE

PAYMENT BY A MISTAKE OF FACT

188. The United States re-alleges paragraphs 1 through 187 above as if fully set forth herein.

189. As a result of Medco Health's conduct, it was paid federal funds from the United States Treasury that were not properly payable.

190. At the time that such payments were made, the United States was not aware of Medco Health's wrongful conduct. Had the United States known that Medco Health was not entitled to receive payments, it would not have approved payment of such funds.

191. The United States is entitled to recover those funds paid by mistake on account of Medco Health's conduct between January.

WHEREFORE, the United States seeks entry of judgment in its favor and against Medco Health in an amount equal to the loss incurred as a result of the payment by mistake.

COUNT SIX

INJUNCTION AGAINST FRAUD-18 U.S.C. § 1345

192. Medco Health is violating and about to violate 18 U.S.C. § 1341 by devising and implementing a scheme or artifice to defraud by depriving patients of its mail order pharmacies of their intangible right of honest services from licensed pharmacies and professional pharmacists, as set forth in this complaint.

WHEREFORE, the United States requests entry of an injunction under 18 U.S.C. § 1345 enjoining the illegal conduct of Medco Health, with respect to all patients of all Medco pharmacies, regardless of payor.

Respectfully submitted,

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